UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

September 1, 2017

MEMORANDUM

Subject: Efficacy Review for SaniDate 15.0,
EPA Reg. No. 70299-26;
DP Barcode #: 440592

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Applicant: BioSafe Systems, LLC
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Formulation from the Label:

Active ingredient:	% by Weight
Hydrogen peroxide	10.0%
Peroxyacetic Acid	15.0%
Other ingredients:	75.0%
Total	100.0%

I. BACKGROUND

The product, SaniDate 15.0 (EPA Reg. No. 70299-26), is an EPA-registered product designed as a general disinfectant and sanitizer. The registrant is requesting to amend the product label to add claims for human health pathogen control in fruits, nut, and vegetable processing water. A protocol review dated May 24, 2016 (MRID 49851601) was performed by the Agency. The submitted study was conducted at Accuratus Lab Services, 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121.

The data package contained a letter to EPA (dated May 16, 2017), EPA form 8570-1 (Application for Pesticide Registration), EPA Form 8570-35 (Data Matrix), 1 efficacy study (MRID No. 50288101), and the proposed product label. Statement of No Data Confidentiality Claims, Good Laboratory Practice Statement, and Quality Assurance Unit Summary were included with the study.

II. USE DIRECTIONS

FOR REDUCTION AND CONTROL OF PATHOGENIC FOODBORNE BACTERIA IN FRUIT VEGETABLE AND NUT PROCESS AND WASH WATERS

Use SaniDate 15.0 to reduce (in 90 seconds) 99.9% of pathogenic food borne bacteria (*Escherichia coli*, *Salmonella enterica*, and *Listeria monocytogenes*) in processing waters for washing fruits, vegetables and nuts.
Directions for raw, post-harvest fruit, vegetable and nut processing waters:

1. Add SaniDate 15.0 batch-wise or continuously to processing water without fruits, nuts or vegetables present at a dilution of 0.8 – 1.9 fl. oz. per 25 gallons of water. This provides approximately 40-100 ppm of peroxyacetic acid and 27-64 ppm of hydrogen peroxide.
2. Allow the solution to circulate at least 90 seconds before adding raw fruits, nuts or vegetables.
3. Adjust dose as needed to maintain a minimum product concentration of 40 ppm of peroxyacetic acid.
4. Allow for a minimum contact time of 90 seconds.
5. Prepare fresh process water daily. Do not reuse water that is badly fouled.
6. Contact your BioSafe Systems technical representative for specific fruit and vegetable applications.

Directions for fresh-cut or processed fruit, vegetable and nut processing waters:

1. Add SaniDate 15.0 batch-wise or continuously to processing water without fruits., nuts or vegetables present at a dilution of 0.8 – 1.5 fl. oz. per 25 gallons of water. This provides approximately 40-80 ppm of peroxyacetic acid and 27-53 ppm of hydrogen peroxide.
2. Allow the solution to circulate at least 90 seconds before adding fresh-cut or processed fruits, nuts and vegetables.
3. Adjust dose as needed to maintain a minimum product concentration of 40 ppm or peroxyacetic acid.
4. Allow for a minimum contact time of 90 seconds. This use complies with the requirements of 21 CFR 173.315(a)(5).
5. Prepare fresh process water daily. Do not reuse water that is badly fouled.
6. Contact your BioSafe Systems technical representative for specific fruit and vegetable applications.

III. SYNOPSIS OF SUBMITTED EFFICACY STUDY

According to the Certificate of Analysis submitted with the studies, the tested concentrations for Lot No. SD15072616SS-A were 10.74% Hydrogen peroxide (H2O2) and 13.99% Peroxyacetic acid (PAA); for Lot No. SD15072616SS-B were 10.63% H2O2 and 15.11% PAA; and for Lot No. SD15072616SS-C were 10.66% H2O2 and 14.84% PAA. The product's nominal concentrations are 10% H2O2 and 15% PAA, and the Lower Certified Limits of the product are 9% H2O2 and 13.5% PAA.

A protocol review dated May 24, 2016 (MRID 49851601) was performed by the Agency.

1. **MRID 50288101 "Efficacy of Antimicrobial Agents to Reduce Foodborne Pathogenic Bacteria in Processing Water for Fruit and Vegetables" Test Organisms: *Listeria monocytogenes* (ATCC 19114, ATCC 19116, ATCC 49594), *Salmonella enterica* (ATCC 6962, ATCC 10721, ATCC 13311), and *Escherichia coli* O157:H7 (ATCC 35150, ATCC 43890, ATCC 43895), for SaniDate 15.0 (EPA Reg. No. 70299-26), by Matthew Sathe, Study conducted at Accuratus Lab Services. Study completion date – March 8, 2017. Project Number: A22611.**

   Study Objective: To determine the efficacy of a product to evaluate a fruit and vegetable wash using a modification of the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants method.

This study was conducted against 3 strains of *Escherichia coli* O157:H7 (ATCC 35150, 43890, 43895), 3 strains of *Salmonella enterica* (ATCC 6962, 10721, 13311), 3 strains of *Listeria monocytogenes* (ATCC 19114, 19116, 49594). Three batches (Nos. SD15072616SS-A, SD15072616SS-B, and SD15072616SS-C) of the product, SaniDate 15.0, were tested using the Accuratus Lab Services protocol #BSS01072415.CUST (copy provided). Each batch was diluted to using 1.00 mL of test substance and the following amount of 400 ppm AOAC Synthetic Hard Water: 4525 mL for lot no. SD15072616SS-A, 4478 mL for lot no. SD15072616SS-B, and 4491 mL for lot no. SD15072616SS-C. The diluent for each batch contains 1% vegetable juice organic soil load. The prepared test substance was used within 90 minutes of preparation. Nine flasks were prepared per batch of product to test the three mixed cultures in triplicate, and each flask was placed into a water bath at 25.0°C and equilibrated for ≥20 minutes. For each strain, 1 loopful of thawed, vortex mixed stock culture was streaked onto Tryptic Soy Agar + 5% Sheep's blood (BAP) for all three organisms and incubated for 22.75 hours at 35-37°C. For the final test culture, 5.0 mL of Phosphate Buffer Dilution Water (PBDW) was added to the plate, and the growth was dislodged from the agar surface. The mixture was transferred to a vessel containing 99.0 mL of PBDW and mixed. Ten agar plates of growth medium were inoculated with 200 µL of culture and incubated for 23 hours at 35-37°C. Five mL of Phosphate Buffer Saline + 0.1% Tween 80 was added to each plate. The culture was dislodged from the agar surface and collected, combined, and mixed. The culture was then filtered through sterile Whatman #2 filter paper using a vacuum source. The culture suspension was diluted with PBDW, and a spectrophotometric analysis was performed using a wavelength of 620 nm. The final absorbance range was 1.369-1.450 for *L. monocytogenes*, 1.619-1.626 for *S. enterica*, and 1.369-1.484 for *E. coli* O157:H7. Equal volumes of the three strains were combined per test organism for the three mixed cultures. Each flask containing 99.0 mL aliquot of test substance was swirled to create enough residual motion of liquid to prevent pooling of the suspension. A 1.00 mL aliquot of culture was added midway between the center and edge of the

surface with the tip of the pipette slightly immersed in the test solution. Each flask was swirled to mix the contents and was exposed for the 90 second exposure time at 25.0°C. Following exposure, 1.00 mL of the inoculated test substance was transferred to 9 mL of neutralizer (Letheen broth + 0.1% sodium thiosulfate + 0.05 catalase). The neutralized contents corresponded to the 10^{-1} dilution. Four 1.00 mL and four 0.100 mL aliquots of the neutralized material were transferred to individual sterile Petri dishes and pour-plated using the subculture agar medium of Tryptic Soy Agar. In addition, three ten-fold serial dilutions were prepared from the neutralizer, representing the 10^{-2}, 10^{-3}, and 10^{-4} dilutions. Four 0.100 mL aliquots of the 10^{-2}, 10^{-3}, and 10^{-4} dilutions were pour-plated. All subcultures were incubated for 24 hours at 35-37°C. Pour-plates were allowed to solidify and were inverted prior to incubation. The subcultures were stored at 2-8°C for one day prior to reading. Following incubation and storage, the subculture plates were visually examined for growth. On 2/9/17, representative test and positive control subcultures showing growth were visually examined, Gram stained and biochemically assayed to confirm or rule out the presence of the test organism. Controls included purity, sterility, initial suspension, numbers, and neutralization confirmation controls.

Note:

Protocol Amendments: No protocol amendment occurred.

Protocol Deviations: No protocol deviations occurred during this study.

IV. RESULTS

Organism	Results: Average Log_{10} CFU/mL (Log_{10} Reduction)			Number Controls CFU/mL (Log_{10})
	SD15072616SS-A	SD15072616SS-B	SD15072616SS-C	
90-second contact time				
Listeria monocytogenes (ATCC 19114, 19116, 49594)	<0.00 (>8.00 LR)	<0.00 (>8.00 LR)	<0.00 (>8.00 LR)	1.01×10^8 CFU/mL ($8.00 \log_{10}$)
Salmonella enterica (ATCC 6962, 10721, 13311)	<0.00 (>7.85 LR)	<0.00 (>7.85 LR)	<0.85 (>7.00 LR)	7.0×10^7 CFU/mL ($7.85 \log_{10}$)
Escherichia coli O157:H7 (ATCC 35150, 43890, 43895)	<0.00 (>7.81 LR)	<0.43 (>7.38 LR)	<0.00 CFU/mL (>7.81 LR)	6.5×10^7 CFU/mL ($7.81 \log_{10}$)

V. CONCLUSION

1. The submitted efficacy data **support** the use of the product, SaniDate 15.0 (EPA Reg. No. 70299-26), as a treatment to reduce pathogenic foodborne bacteria in fruit and vegetable process waters when diluted using 1 mL of product in 4525 mL (SD15072616SS-A), 4478 mL (SD15072616SS-B), and 4491 mL (SD15072616SS-C) of 400 ppm AOAC Hard Water for a 90-second contact time and 25°C in the presence of 1% vegetable juice organic soil load against the following microorganisms:

MRID	Organisms
50288101	*Listeria monocytogenes* (ATCC 19114, 19116, 49594)
	Salmonella enterica (ATCC 6962, 10721, 13311)
	Escherichia coli O157:H7 (ATCC 35150, 43890, 43895)

According to the analysis of the active ingredient concentration for each product batch, the tested concentrations were at or below the lower certified limits of the active ingredients. Killing was observed in the subcultures of the required number of replicates tested against the required number of product lots. Neutralization confirmation testing showed passing results. Purity controls were reported as pure. Sterility controls did not show growth.

VI. LABEL RECOMMENDATIONS (for proposed label version V7 May 9, 2017)

1. The proposed label claims are **acceptable** regarding the use of the product, SaniDate 15.0 (EPA Reg. No. 70299-26), to reduce and control pathogenic foodborne bacteria in processing waters used for washing fruits and vegetables, at a dilution of 0.8 – 1.9 fl. oz. per 25 gallons of water or 0.8 – 1.5 fl. oz. per 25 gallons on water, for a 90-second contact time against the following organisms:

   Listeria monocytogenes (ATCC 19114, 19116, 49594)
   Salmonella enterica (ATCC 6962, 10721, 13311)
   Escherichia coli O157:H7 (ATCC 35150, 43890, 43895)

   These claims **are supported** by the applicant's data.

2. Remove any claims for nut/s throughout the label where public health uses are indicated. The protocol supports treatment of process water for fruits and vegetables.

3. For the DIRECTIONS FOR USE for reducing and controlling of pathogenic foodborne bacteria in fruit and vegetable process and wash waters for post-harvest fruits and vegetables (pg. 2), the instruction to "Adjust dose as needed to maintain a minimum product concentration of 40 ppm or peroxyacetic acid" should also specify the dilution unit in fl. oz., and the label should instruct users to maintain dosing by adding the minimum of 0.8 fl. oz. to 25 gallons of water. Label should also recommend the use of test strips or other methods to monitor the concentration in ppm.

4. Remove "Directions for fresh-cut or processed fruit, vegetable and nut processing waters" from the Directions for Use for Reduction and Control on Pathogenic Foodhorne Bacteria in Fruit and Vegetable and Nut Process and Wash Waters section of the label. This is an FDA use and should be separated and approved accordingly along with other FDA uses. FDA uses and claims on the label should be distinctly separated from uses and claims pertaining to EPA jurisdiction.

5. Remove the use for room fogging application to control non-public health organisms (pages 3, 10, 11, and 12). This also includes any claims of effectiveness as a fogger or fogging system. The Agency does not allow this use without submitted efficacy data conducted according to our room fogging protocol guidance. Additionally, fogging application cannot be used as an adjunct.

6. On page 8 of the proposed label, under Disinfection Use Directions, the instruction "For moderately soiled surfaces a pre-cleaning step is not required..." should be changed to "For lightly soiled surfaces a pre-cleaning step is not required" or "For visibly cleaned surfaces a pre-cleaning step is not required".

7. On page 17, the claim to "Use SaniDate 15.0 in cooling water systems" should specify "to control non-public health and slime-forming microorganisms".

8. On page 18, remove "fogging (wet misting) systems" from the claim "SaniDate 15.0 may be applied through automatie washing systems, immersion tanks, low pressure sprayers and fogging (wet misting) systems."